(g) The term *proceeding* means all actions taken for the issuance, amendment, or repeal of any rule issued pursuant to section 201 of the Act, commencing with the publication by the Administrator of the proposed rule, amended rule, or repeal in the FEDERAL REGISTER.

(h) Any term not defined in this section shall have the definition set forth in section 102 and 1001 of the Act (21 U.S.C. 802 and 951) and § 1301.02 of this chapter.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 15317, Apr. 23, 1986; 56 FR 5754, Feb. 13, 1991]

§ 1308.03 Administration Controlled Substances Code Number.

(a) Each controlled substance, or basic class thereof, has been assigned an ''Administration Controlled Substances Code Number'' for purposes of identification of the substances or class on certain Certificates of Registration issued by the Administration pursuant to §§ 1301.44 and 1311.43 of this chapter and on certain order forms issued by the Administration pursuant to § 1305.05(d) of this chapter. Applicants for procurement and/or individual manufacturing quotas must include the appropriate code number on the application as required in §§ 1303.12(b) and 1303.22(a) of this chapter. Applicants for import and export permits must include the appropriate code number on the application as required in §§ 1312.12(a) and 1312.22(a) of this chapter. Authorized registrants who desire to import or export a controlled substance for which an import or export permit is not required must include the appropriate Administration Controlled Substances Code Number beneath or beside the name of each controlled substance listed on the DEA Form 236 (Controlled Substance Import/Export Declaration) which is executed for such importation or exportation as required in §§ 1312.18(c) and 1312.27(b) of this chapter.

(b) Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Administration Controlled Substances Code Number for any purpose.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 51 FR 15318, Apr. 23, 1986]

§ 1308.04 Submission of information by manufacturers.

(a) Each person who manufactures, packages, repackages, labels, relabels, or distributes under his own label any product (including any compound, mixture, or preparation, diagnostic, reagent, buffer, or biological) containing any quantity of any controlled substance (whether such product is itself controlled or is excepted, exempted, or excluded from some or all controls pursuant to § 1308.21–24 or § 1308.31–32) shall submit information required in paragraph (b) of this section for each such product being manufactured or sold on July 1, 1972. The information should be submitted by registered mail, return receipt requested, to the Regulatory Support Section, Attention: Project Label, Drug Enforcement Administration, Department of Justice, Washington, DC 20537, by August 31, 1972. In the case of new products manufactured after July 1, 1972, or new dosage forms or other unit forms manufactured after July 1, 1972, or changes in information submitted by August 31, 1972, the registrant shall submit the information regarding such item within 30 days after the date on which the manufacture commences or information change occurs. In the case of products, the manufacture of which is discontinued after July 1, 1972, the registrant shall submit notice of such discontinuance within 30 days after the date on which manufacture ceases. In the case of products the manufacture of which was discontinued before July 1, 1972, which are still being sold, the registrant shall submit a notice of such discontinuance with his initial submission.

(b) Two labels or other documents reflecting the following information shall be submitted with reference to each dosage form or other unit form of each item containing any quantity of any controlled substance:

(1) The trade name, brand name, or other commercial name of the product;